EXPRESS MAIL MAILING LABEL	
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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Kathryn F. Sykes and Stephen A. Johnston	Group Art Unit: Unkown
Serial No.: UNASSIGNED	Examiner: Unknown
Filed: Concurrently Herewith	Atty. Dkt. No.: UTSD:557USD1/MBW
For: LINEAR AND CIRCULAR EXPRESSION ELEMENTS	

PRELIMINARY AMENDMENT

Commissioner for Patents
Washington, D.C. 20231

Commissioner:

Please amend this application as follows:

In the Specification

At Page 1, please delete the word "Provisional" from the line reading "Provisional Application For Letters United States Patent."

At page 2, please delete the paragraph spanning lines 2-5.

At page 2, please insert the following paragraph at line 2:

--This is a continuation application of co-pending application Serial No. 09/535,366 filed March 24, 2000, which claims priority to U.S. Provisional Application Serial No. 60/125,864,

filed March 24, 1999 and U.S. Provisional Application Serial No. 60/127,22, filed March 31, 1999, each of which disclosures is specifically incorporated herein by reference in its entirety.--

At page 5, please amend the paragraph spanning lines 7-10 as follows:

The nucleic acid segment containing the ORF, putative ORF, or any other nucleic acid segment which is comprised in a LEE or CEE may be obtained from any of a variety of sources. For example, it may be obtained by PCR®, from a linear nucleic acid that is cut out of a plasmid, or obtained by synthesis.

In the Claims

Cancel claims 1-96, without prejudice, or disclaimer.

Please add new claims 97-122 as follows:

--97. (New) A composition comprising one or more antigen, the one or more antigen determined by a method comprising:

preparing *in vitro* a plurality of linear or circular expression elements produced by a method comprising:

obtaining plurality of DNA segments comprising an open reading frame; and

linking open reading frames to promoters to create a plurality of linear or circular expression elements;

introducing the plurality of linear or circular expression elements into an animal; and

selecting from the plurality of linear or circular expression elements one or more open reading frames that encode an antigen effective to generate an immune response.

98. (New) The composition of claim 97, further defined as comprising one or more cancer antigen.

99. (New) The method of claim 97, further defined as comprising one or more pathogen antigen.

100. (New) The composition of claim 99, wherein the one or more pathogen antigen is a one or more virus, bacterium, fungus, alga, protozoan, arthropod, nematode, platyhelminthe, or plant antigen.

101. (New) The composition of claim 99, wherein the one or more pathogen antigen is a virus antigen.

102. (New) The composition of claim 99, wherein the one or more pathogen antigen is a bacterium antigen.

103. (New) The composition of claim 99, wherein the one or more pathogen antigen is a fungus antigen.

104. (New) The method of claim 97, wherein at least one of the DNA segments comprising an open reading frame is produced *in vivo* and then non-covalently linked to the promoter *in vitro*.

105. (New) The method of claim 97, wherein at least one of the DNA segments comprising an open reading frame is obtained by using a polymerase chain reaction.

106. (New) The method of claim 97, wherein at least one of the DNA segments comprising an open reading frame is obtained by chemical synthesis.

107. (New) The composition of claim 97, wherein linking open reading frames to promoters comprises non-covalent linking.

108. (New) The composition of claim 97, wherein preparing the plurality of linear or circular expression elements further comprises linking open reading frames to terminators.

109. (New) The composition of claim 108, wherein linking open reading frames to terminator comprises non-covalent linking.

110. (New) The composition of claim 97, wherein the linear or circular expression element is injected into the organism.

111. (New) The composition of claim 97, wherein the organism is an animal.

112. (New) The composition of claim 97, wherein the animal is a human.

113. (New) The composition of claim 97, wherein the plurality of linear or circular expression elements comprises open reading frames encoding at least one polypeptide from a cancer cell.

114. (New) The composition of claim 97, wherein the plurality of linear or circular expression elements comprises open reading frames encoding at least one polypeptide from a pathogen.

115. (New) The composition of claim 114, wherein the pathogen is a virus, bacterium, fungus, alga, protozoan, arthropod, nematode, platyhelminthe, or plant.

116. (New) The composition of claim 114, wherein the pathogen is a virus.

117. (New) The composition of claim 116 wherein individual linear or circular expression elements encoding all potential allergens of a virus is comprised in the plurality of types of linear or circular expression elements.

118. (New) The composition of claim 114, wherein the method of determining the antigen further comprises testing the animal against challenge with the pathogen.

119. (New) The composition of claim 118, wherein the animal is protected against challenge with the pathogen.

120. (New) The method of claim 119, wherein the animal is a mammal.

121. (New) The composition of claim 97, wherein the composition is further defined as comprised in a pharmaceutical composition.

122. (New) The composition of claim 97, wherein the composition is further defined as effective, in appropriate dosage, to produce a protective response in an animal.--

Appendix A contains the amended paragraph of page 5, lines 7-10 with appropriate editing indicia. Appendix B contains a clean copy of the added and edited parts of the specification as believed to exist after the amendments. Appendix C contains a copy of the pending claims, after editing of the amendments.

REMARKS

Claims 1-96 were prosecuted in the parent case, application Serial No. 09/535,366 and thus have been canceled from this continuation application. New claims 97-122 have been added by amendment. Support for these claims is found in the original specification and the claims as filed in the original case. The parent application was allowed on January 17, 2002, but has not yet issued.

Therefore, the active claims in this case are claims 97-122.

The specification has been amended to recite the relationship with the parent case, and a correction of a minor typographical error at the first page and the fifth page.

It is believed that no fee is due; however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be required for any reason, the Commissioner is authorized to deduct said fees from Fulbright & Jaworski L.L.P. Account No.: 50-1212/10200687/MBW.

Respectfully submitted,

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Date: February 15, 2002

APPENDIX A:- COPY OF AMENDMENT TO SPECIFICATION WITH EDITING INDICIA

The paragraph at page 5, lines 7-10 has been amended as follows:

The [he] nucleic acid segment containing the ORF, putative ORF, or any other nucleic acid segment which is comprised in a LEE or CEE may be obtained from any of a variety of sources. For example, it may be obtained by PCR®, from a linear nucleic acid that is cut out of a plasmid, or obtained by synthesis.

APPENDIX B:- CLEAN COPY OF NEW/EDITED PORTIONS OF THE SPECIFICATION AFTER AMENDMENT

The following paragraph has been inserted at page 2, line 2:

This is a continuation application of co-pending application Serial No. 09/535,366 filed March 24, 2000, which claims priority to U.S. Provisional Application Serial No. 60/125,864, filed March 24, 1999 and U.S. Provisional Application Serial No. 60/127,22, filed March 31, 1999, each of which disclosures is specifically incorporated herein by reference in its entirety.

The paragraph at page 5, lines 7-10, as amended is as follows:

The nucleic acid segment containing the ORF, putative ORF, or any other nucleic acid segment which is comprised in a LEE or CEE may be obtained from any of a variety of sources. For example, it may be obtained by PCR®, from a linear nucleic acid that is cut out of a plasmid, or obtained by synthesis.

<u>**APPENDIX C: COPY OF PENDING CLAIMS AFTER AMENDMENT**</u>

97. A composition comprising one or more antigen, the one or more antigen determined by a method comprising:

preparing *in vitro* a plurality of linear or circular expression elements produced by a method comprising:

obtaining plurality of DNA segments comprising an open reading frame; and

linking open reading frames to promoters to create a plurality of linear or circular expression elements;

introducing the plurality of linear or circular expression elements into an animal; and

selecting from the plurality of linear or circular expression elements one or more open reading frames that encode an antigen effective to generate an immune response.

98. The composition of claim 97, further defined as comprising one or more cancer antigen.

99. The method of claim 97, further defined as comprising one or more pathogen antigen.

100. The composition of claim 99, wherein the one or more pathogen antigen is a one or more virus, bacterium, fungus, alga, protozoan, arthropod, nematode, platyhelminthe, or plant antigen.

101. The composition of claim 99, wherein the one or more pathogen antigen is a virus antigen.

102. The composition of claim 99, wherein the one or more pathogen antigen is a bacterium antigen.

103. The composition of claim 99, wherein the one or more pathogen antigen is a fungus antigen.

104. The method of claim 97, wherein at least one of the DNA segments comprising an open reading frame is produced *in vivo* and then non-covalently linked to the promoter *in vitro*.

105. The method of claim 97, wherein at least one of the DNA segments comprising an open reading frame is obtained by using a polymerase chain reaction.

106. The method of claim 97, wherein at least one of the DNA segments comprising an open reading frame is obtained by chemical synthesis.

107. The composition of claim 97, wherein linking open reading frames to promoters comprises non-covalent linking.

108. The composition of claim 97, wherein preparing the plurality of linear or circular expression elements further comprises linking open reading frames to terminators.

109. The composition of claim 108, wherein linking open reading frames to terminator comprises non-covalent linking.

110. The composition of claim 97, wherein the linear or circular expression element is injected into the organism.

111. The composition of claim 97, wherein the organism is an animal.

112. The composition of claim 97, wherein the animal is a human.

113. The composition of claim 97, wherein the plurality of linear or circular expression elements comprises open reading frames encoding at least one polypeptide from a cancer cell.

114. The composition of claim 97, wherein the plurality of linear or circular expression elements comprises open reading frames encoding at least one polypeptide from a pathogen.

115. The composition of claim 114, wherein the pathogen is a virus, bacterium, fungus, alga, protozoan, arthropod, nematode, platyhelminthe, or plant.

116. The composition of claim 114, wherein the pathogen is a virus.

117. The composition of claim 116 wherein individual linear or circular expression elements encoding all potential allergens of a virus is comprised in the plurality of types of linear or circular expression elements.

118. The composition of claim 114, wherein the method of determining the antigen further comprises testing the animal against challenge with the pathogen.

119. The composition of claim 118, wherein the animal is protected against challenge with the pathogen.

120. The method of claim 119, wherein the animal is a mammal.

121. The composition of claim 97, wherein the composition is further defined as comprised in a pharmaceutical composition.

122. The composition of claim 97, wherein the composition is further defined as effective, in appropriate dosage, to produce a protective response in an animal.